“Industry” Perspective on State Roles in the Responsible Development of Nanotechnologies

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THE NANOBUSINESS ALLIANCE

We are the U.S. National Trade Organization for firms developing and using nanotechnologies as part of their businesses.

It is our mission to help entrepreneurs and innovators bring affordable, life-improving nanotech products to the public by creating a positive policy climate, a supportive community for nanotech innovators and by educating the marketplace

NBA: Our Members Represent a Wide Variety of Industries

- **Automotive**
- **Instrumentation manufacturers**
- **Specialty chemicals**
- **Consumer and Industrial electronics**
- **Environmental sensors**
- **Medical devices**
- **Pharmaceuticals**
- **Industrial coatings**
- **Aviation**
- **Optics**
- **Cosmetics**
- **Plastics**
- **Consumer Appliances**
- **Water purification**
- **Energy storage**

In most cases, development and application of nanotechnologies involves extension of current product capabilities – not whole new products

The Nanotechnology Industry is Extremely Diverse in it Applications

- **"Nanotechnology" is not a particular product or process**
- **Nanotechnology refers to a *wide range of technologies* to manipulate and position matter at the nanoscale level – most of which have not been invented yet.**
- ***As evidenced by our membership*, these technologies are employed in a wide range of industries for a variety of purposes**
- **As a result, real world development and use of "nanotechnologies" are likely to be quite dissimilar from one company to the next**

Societal Use and Exposure to "Nanomaterials" is Not New.

Our air is filled with ultrafine (nano) particles…

- **Combustion particulate by-products (exhaust)**
- **Welding fumes**
- **Cooking fumes**
- **Vehicle Tire attrition particles**
- **Carbon blacks, fumed silicas, etc.**
- **Ink and dye components**
- **Natural combustion particulate by-products (volcanoes, forest fires)**
- **Sea spray, crustal erosion, etc.**

Indeed, it is what we have learned about the *risks of these "conventional" particles* in ambient and workplace air studies that has raised the concerns with intentionally produced ultrafine (nano) particles in the first place. The difference is that intentionally produced particles are engineered to maximize commercial properties and minimize harm.

Societal Use and Exposure to "Nanomaterials" is Not New

Implications:

- There *is* reason to exercise caution
- *No* reason to believe that intentionally produced "nanomaterials" (as a generic class) inherently present abstract "hazard" that is ***either greater than or less than*** more familiar ultrafine particles
- Some will be more hazardous than others
- Society has extensive experience in effectively controlling exposure to ultrafine particles
- *Intentionally produced* ultrafine particles are less likely to be released (they are product, not waste)

Intentionally Produced "Nanomaterials" Represent a Massively Diverse Set

This diversity makes generalizations about the entire class impossible

- "The only true statement you can make about them [as a group] is that they are small." – Scott Walsh, Environmental Defense
- Compare: Try to generalize the life-cycle hazards of all "meter-scale" products – everything from Axes to Zenith televisions -- or "all organic chemicals"
- And as above, the nano-size scale is not unique to engineered nanomaterials

Intentionally Produced "Nanomaterials" Represent an Massively Diverse Set

Vast Variety of Chemicals/Materials

- each may have surface treatments

Vast Variety of Shapes

- Quantum Dots, Metal Oxides, Metal Particles, Dendrimers, Carbon Nanotube (Chirality, Number of Walls, Length, Diameter)

Vast Variety of Formats

- Powders, Polymers, Gels, Solutions, Sheets etc.

Vast Variety of Manufacturing, Use and Exposure Contexts

- Automotive fuel systems, microchip handling equipment, sunscreens, Fabric Coatings, Lens Cleaner; Solar Cells; Paints and Coatings

Taken together these can generate a staggering number of combinations

Intentionally Produced "Nanomaterials" Represent an Massively Diverse Set

- Given the diversity of materials and manufacturing and use contexts, "one-size fits all" thinking or policy is inadequate and bound to have unintended consequences.
- Generalized statements about "nanomaterials" are only warranted to the extent tied to their scale.
- To be balanced, discussions and statements about scale-related characteristics should be given full context and include reference to incidental and historically used ultrafine particles unless a reasoned (non-arbitrary) distinction can be made.

Most of the "Uncertainties" and Concerns Ascribed to Nanotechnologies Are Not Unique to Nanomaterials

- The potential to be both hazardous and benign
- The various properties exhibited
- Absence of exposure & environmental release standards
- Absence of chronic hazard information
- Absence of life cycle fate, transport and exposure information
- Diversity of materials
- Uncertainty how existing laws will apply and whether sufficient to control risk
- Absence of *required* pre-market toxicological testing
- Limitations of EPA's, CPSC's, FDA's [etc.] pre-market safety review procedures, authorities
- The special challenges of particle toxicology

Many of the "Uncertainties" and Concerns Ascribed to Nanotechnologies Are Not Unique to Nanomaterials

Implication:

- Nanomaterials developers / users should be held to same standards (no more no less) as other users / developers of materials of equivalent uncertainty and exercise equivalent caution
- Generic chemical regulation issues should be addressed in a non-discriminatory fashion

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Existing Regulatory Frameworks apply to Nanomaterials and Nanotechnology Processes

Activity	Act	Agency
Pre-market Review; Monitoring / regulation of Chemicals in Commerce	Toxic Substances Control Act (TSCA)	EPA
Reporting of and Response to Problematic Environmental Releases	Comprehensive Environmental Response Compensation and Liability Act (CERCLA)	EPA **State Analogues**
Waste Management	Resource Conservation and Recovery Act (RCRA)	EPA **State Delegated Programs**
Release into Air Releases to POTWs, Water	Clean Air Act, Clean Water Act, Safe Drinking Water Act	EPA **State Delegated Programs**
Workplace Safety, Exposure	Occupational Safety and Health Act (OSHA)	OSHA, NIOSH, **State equivalent programs**
Consumer Safety	Food, Drug and Cosmetics Act (FDCA)	Consumer Products Safety Commission (CPSC), Food and Drug Administration (FDA)

We agree with EPA that existing frameworks are adequate to control risks.

Existing Regulatory Frameworks apply to Nanomaterials and Nanotechnology Processes

- How these frameworks should *apply* to particular nano materials and processes – *as with all other materials and processes* – will have to be determined one-at-a-time, as the issues arise, based on reason and best available information.
- Where uncertainties exist, regulatory treatment should be on par with materials and processes of like uncertainty (proportionality)
- *As the primary implementers of most federal environmental laws, States will be on the front line of many of these questions*

Traditional bulk chemical manufacturing is probably the wrong conceptual model for most firms applying nanotechnologies

- Some nanomaterials will be produced and sold in bulk like many conventional chemicals.
- But the “trick” to most novel applications (e.g., in electronics) is developing a method to properly position a clean, well formed nanostructured material on or in a device. This likely means that many nanomaterials will be manufactured “in place” and not distributed as free materials.

Perhaps more than most, nanotechnology entrepreneurs are sensitive to proprietary process confidentiality

- Their competitive advantage lies in translating the theoretical into practical, feasible applications
- Patent position and painstakingly developed, proprietary “know-how” may be their key assets.

Suggested Roles for Commonwealth EHS Agencies

- **Be Aware of Take-Away Points Presented in Slides Above**
- **Build Agency Capacity:** Develop core competency to deliver timely, informed, consistent, and dispassionate nanotechnology-related regulatory decisionmaking as the need arises (e.g., permitting):
  - Inter- and Intra-Agency workgroups of experts
  - Equipped to view uncertainties in full context, e.g., leveraging existing knowledge of ultrafines
  - Liaise with EPA, NIOSH emerging expertise
  - Learn from industry – ***NBA can help***
- **Review, Compile and Distribute Worthy and Practicable "best practice" documents to businesses**

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